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# Gentle insertion, secure fixation: Evaluating the electrode holder of the Cochlea Hydrodrive

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*Abstract: The slow and steady insertion of cochlear implant electrode arrays using automated insertion devices promises gentle implantation with potentially better hearing results for patients. The Cochlea Hydrodrive is a cost-effective and precise hydraulic insertion tool, which enables ultra-slow electrode insertions. In this study, we present the experimental evaluation of the electrode holder for this device, focusing on secure electrode fixation, handling and release in order to increase reliability for future clinical applications.*



## I. Introduction

The cochlear implant (CI) is a neuroprosthesis used to restore hearing in patients with severe to profound sensorineural hearing loss. In CI surgery, the insertion of the electrode array (EA) of the implant into the inner ear is a highly critical step regarding intracochlear trauma. When delicate structures inside the cochlea are damaged, residual hearing may be lost, resulting in a deteriorated hearing outcome [1]. Recent studies have found that slow and steady insertions can reduce occurring insertion forces [2, 3] thereby minimizing intracochlear trauma [4]. That is why surgical assistance devices have been developed in order to automate this procedure for a more standardized and steady EA insertion [5].

A hydraulically driven system for automated EA insertion is the *Cochlea Hydrodrive* (CHD, see Fig. 1a) [6, 7]. The actuation concept of the CHD is based on a syringe, which is connected to an infusion pump via infusion lines. Once the pump is activated, fluid is fed into the syringe, causing a forward movement of the syringe plunger. The EA is clamped into an electrode holder (see Fig. 1b), which is connected to the plunger. This holder moves within an additional guide tube consisting of a slotted stainless-steel tube, which guides the silicone body of the EA along its path towards the entrance into the cochlea. This significantly reduces EA buckling and associated forces while also facilitating the alignment of the insertion trajectory of the tool [3]. The CHD is fixated to the patient's head using a flexible arm and a surgical retractor. This study focuses on the iterative design process and experimental evaluation of the electrode holder of the CHD to ensure a secure hold of the EA without affecting its functionality.

## II. Material and methods

For this study, the electrode holder was designed to hold MED-EL FLEX Series EAs (MED-EL, Innsbruck, Austria). The electrode is grasped by the u-shaped electrode holder on the so-called electrode lead – the part of the electrode that remains outside the cochlea. This silicone-based lead has an outer diameter of 1.3 mm. In order to find a suitable electrode holder, eight different prototypes were designed, varying in clamping diameter and length of the u-shaped clamping area (see Fig. 1c).

The secure fixation of the EA within the holder was evaluated in two scenarios. In both scenarios, the different prototypes were tested consecutively in a previously established insertion test setup [8]. A Flex28 EA was

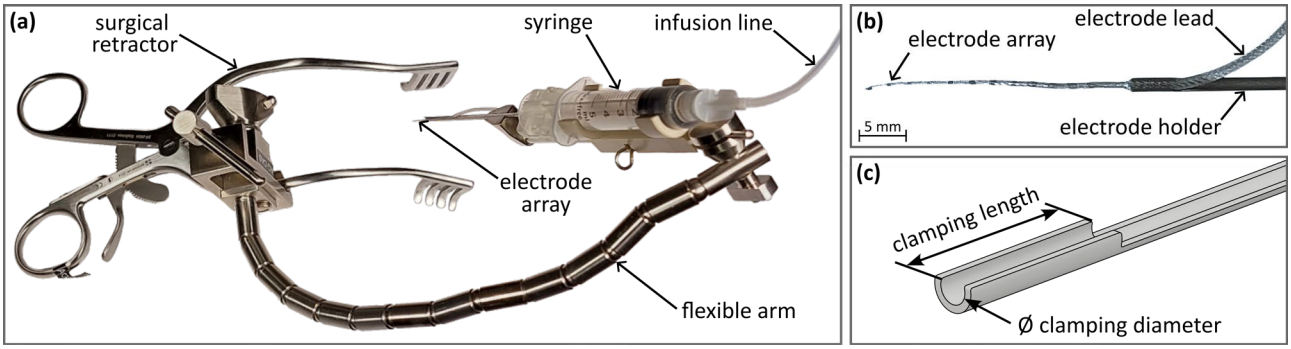


*Figure 1: (a) The Cochlea Hydrodrive system; (b) EA clamped into the electrode holder; (c) Representative isometric view of the clamping area of the electrode holder with labels for the prototype dimensions varied in the experiments*

clamped into the prototypes, as intended. In the first scenario, the EA was inserted automatically (0.1 mm/s) into a tilted cochlear model [3] without lubrication, to provoke kinking and buckling of the EA (see Fig. 2a). This was aimed to test, whether the corresponding prototype is able to hold the EA in a highly unfavorable insertion setting, as poor lubrication leads to the highest forces on the electrode [9]. In the second scenario, the EA was clamped between two plates to fixate it below the lead (see Fig. 2b). The electrode holder was pushed (0.1 mm/s) and the force below the fixation plates was measured using a force sensor (K3D35, ME-Messsysteme, Hennigsdorf, Germany). In this setting, the axial force that causes the EA to slip out of the holder was determined. In both scenarios, the tests were performed n = 5 times per prototype.

The most promising electrode holder prototype from the aforementioned tests was used for an additional EA integrity assessment to evaluate, if the clamping process into the electrode holder affects the EA functionality. For this purpose, three additional Flex28 EAs were used, which had passed electrical testing by the manufacturer. Two test subjects clamped each EA into the electrode holder and subsequently released it by gently pushing a surgical needle between the electrode holder and EA. This process was repeated 15 times per EA. Microscope photos of every EA were captured before and after all clamping experiments. Finally, the electrical function tests were repeated for the tested EAs by the manufacturer.

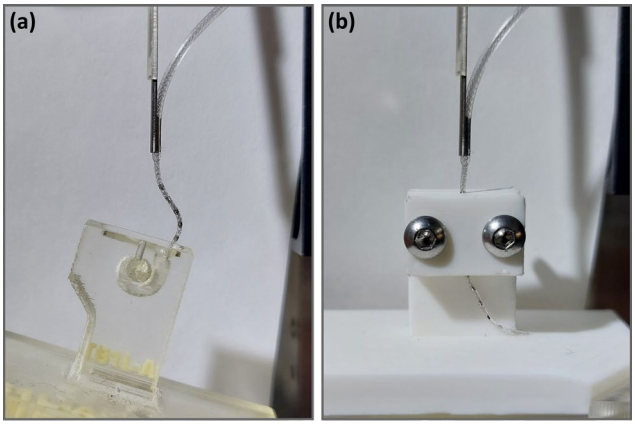


*Figure 2: Electrode fixation tests: (a) unfavorable insertion with electrode buckling; (b) axial clamping force*

## III. Results and discussion

All prototypes passed the first scenario of the fixation tests. Although the EA buckled significantly in each case, it did not detach from the holder. In the second scenario, the EA began to slip out axially at forces of approx. 40 to 50 mN on all prototypes with an inner diameter of 1.3 mm. This would not be suitable for intraoperative use, as axial peak forces from in vivo insertions are reported to reach values of up to 102.4 mN [10]. In all prototypes with a smaller diameter, the EA remained securely fixated without slipping, regardless of the clamping length, up to an axial force of 200 mN, which was defined as termination criterion. The further decision for the clamping length was made based on feedback from a senior CI surgeon. The deciding factors were the ease and intuitiveness of clamping and releasing the EA, which was rated optimal for the shortest clamping length.

Therefore, this prototype was selected and subsequently used for the EA integrity assessment. Here, the evaluation of the microscope photos of the EAs did not show any physical damage of the silicone body due to repeated clamping and releasing. The post-experimental electrical tests performed by the manufacturer were passed by all three EAs. The conductivity on all 12 channels was unaffected with no detectable wire breakages or short circuits, showing the electrical integrity of the EA. Although this study focuses on one series of EAs, the holder design can be readily adapted for use with EAs from other manufacturers in future research.

## IV. Conclusions

This study describes the development and evaluation of an electrode holder for automated EA insertions using the *Cochlea Hydrodrive*. The experimental results show that the final design provides a secure mechanical fixation while also ensuring the integrity of the implant. Additionally, a senior CI surgeon confirmed its applicability in CI surgery. Based on these results and the extensive preclinical validation [3, 6, 7, 11], a first clinical study involving the *Cochlea Hydrodrive* has been approved in 2025 and is currently in progress to validate whether these promising results can be translated into patient care.

### AUTHOR'S STATEMENT

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